Clinical Data Update System (CDUS) v3.0

Updates and Clarifications made to the January 28, 2002 Notice of Modifications

May 3, 2002

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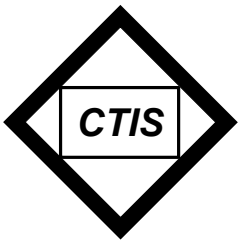

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By Capital Technology Information Services, Inc.

Updates and Clarifications Made to the January 28, 2002 Notice of Modifications

Funding Information

All references to the collection of funding information were removed. This includes references made to the Current_Funding_Flag in the COLLECTIONS and CORRELATIVE_STUDY tables, the PROTOCOL_FUNDING and CORRELATIVE_FUNDING tables, the CDUS Smart Loader Sample File, the New and/or Revised Business Rules, and the Summary. The following provides the specific sections affected in the January 28, 2002 Notice of Modifications and the type of revision.

Original Section Name and Number		Revision
1.1.2	Current Funding Flag	Removed
1.2.1	Current Funding Flag	Removed
2.4	PROTOCOL_FUNDING_TABLE	Removed
2.5	CORRELATIVE_FUNDING_TABLE	Removed
3	CDUS Smart Loader Sample File	Revised
6	New and/or Revised Business Rules	Revised
Appendix A: Summary List of Modifications		Revised

Clarifications and Editorial Modifications

1.3.3 Off Study Date and 1.3.4 Off Study Reason, pg. 4: These sections were switched to reflect their placement within the PATIENTS Table (the sections are now numbered **1.3.3 Off Study Reason** and **1.3.4 Off Study Date**).

1.4 TREATMENT_COURSES TABLE, pg. 6: The word "Table" appearing first in the section title was removed.

1.6.3 Adverse Event - Other, Specify, pg. 7: Minor typographical revisions were made for consistency.

2.2. BASELINE_ABNORMALITIES TABLE, pg. 12: The word "toxicities" was changed to "Adverse Events" in the following sentence: Baseline abnormality information will provide CTEP with a baseline to use when analyzing treatment-related **toxicities**.

4.1 OFF TREATMENT REASON, pg. 16: This section title was renamed to reflect both the field and table name (the section is now named **OFF_TREATMENT_REASON FROM THE PATIENTS TABLE**).

4.1 OFF TREATMENT REASON, pg. 16: The new and removed values were formatted as columns to be consistent with Sections 4.2 and 4.3.

4.2 PRIOR THERAPIES, pg. 16: This section title was renamed to reflect both the field and table name (the section is now named **THERAPY_CODE FROM THE PRIOR_THERAPIES TABLE**).

4.3 DOSE UNIT CODE, pg. 16: This section title was renamed to reflect both the field and table name (the section is now named **UNIT_CODE FROM THE COURSE_AGENTS TABLE**). The value "mVP" was updated to "MVP."

4.4 PATIENT RACE AND PATIENT ETHNICITY, pg. 17: This section title was renamed to reflect both the field and table name (the section is now named **RACE_CODE FROM THE PATIENT RACES TABLE AND ETHNICITY_FLAG FROM THE PATIENTS TABLE**).

4.5 INTERNATIONAL MEDICAL TERMINOLOGY (IMT) AND MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MedDRA) TERMINOLOGY, pg. 17: This section was updated to specify the field names and tables affected by the change from IMT to MedDRA codes.

4.4 PATIENT RACE AND PATIENT ETHNICITY, pg. 17: The Hispanic Race Code was updated from (2) to (02).

5.1 DOSE_AMOUNT, pg. 18: This section was updated to clarify that the total number of spaces available for entry as 20. If needed, 17 spaces can be used for digits with an additional three spaces available for decimal places.

Updates to Section 1: New Information to be Collected – Changes to Existing Tables

1.3.3 Off Study Reason, pg. 4: The word "period" was removed from the following valid value description:
01 = Protocol-defined follow-up **period** completed.

1.3.3 Off Study Reason, pg. 4: The word "toxicity" was replaced with "Adverse Event" for the following valid value description: 05 = **Toxicity**/Side Effects/Complications.

1.3.3 Off Study Reason, pg. 4: "Other" (98) was added to the list of Off_Study_Reason valid values.

1.3.4 Off Study Date, pg. 4: The section was updated to clarify that any value given for Off_Study_Reason would require entry of the Off_Study_Date.

1.3.8 Technical Reporting Requirements, pg. 5: The attribute for the Ethnicity_Flag was updated fromVarchar2(2) to Varchar2(1).

1.4.1 Field Name and Attribute Change, pg. 6: The original field name (Tox_Experience) and the new field name (AE_Experience) were changed to past tense (Tox_Experienced and AE_Experienced). The section was updated to better reflect the change to the Course_ID field.

1.5 COURSE_AGENTS TABLE, pg. 6: The section was updated to better reflect the change to the Course_ID field.

1.6.2 Field Name and Attribute Change, pg. 6: The section was updated to better reflect the change to the Course_ID field.

1.6.3 Adverse Event – Other, Specify, pg. 7: The term "toxicity type" was replaced with "AE_Type_Code" in the following sentence: The AE_Other_Specify field was added to the ADVERSE_EVENTS table to collect the name of the Adverse Event when a **toxicity type** of 'Other, Specify' is selected.

1.6.5 Technical Reporting Requirements, pg. 8: The placement of the AE_Other_Specify element within the ADVERSE_EVENTS table was modified to group the primary key elements together.

1.6.5 Technical Reporting Requirements, pg. 8: The Course_ID field was updated from "Number6(1)" to "Number(6)."

1.7 TRIAL_COMMENTS TABLE, pg. 8: This section was added to reflect a field name change.

1.8 PHASE1_END_POINT_DLTS TABLE, pg. 8: This section was added to reflect a field name change.

Updates to Section 1: New Information to be Collected – New Tables

2.1.5 Technical Reporting Requirements, pg. 12: The attribute for the Patient_ID column was updated from Varchar2(10) to Varchar2(20).

2.2.1 Technical Reporting Requirements, pg. 12: The placement of AE_Other_Specify element within the BASELINE_ABNORMALITIES table was modified to group the primary key elements together.

2.2.1 Technical Reporting Requirements, pg. 12: The attribute for the Patient_ID column was updated from Varchar2(10) to Varchar2(20).

2.3.1 Technical Reporting Requirements, pg. 13: The placement of AE_Other_Specify element within the LATE_ADVERSE_EVENTS table was modified to group the primary key elements together.

2.3.1 Technical Reporting Requirements, pg. 13: The attribute for the Patient_ID column was updated from Varchar2(10) to Varchar2(20).

Updates to Section 3: CDUS Smart Loader Sample File, pg. 15

The PATIENTS table was updated to reflect a varchar field (with quotation marks) for Off_Study_Reason.

The COURSE_AGENTS table was updated to reflect a number field (without quotation marks) for Course_ID and to reflect the Unit_Code as lower case.

The sample file was updated to reflect the placement changes described above for the ADVERSE_EVENTS, BASELINE_ABNORMALITIES, and LATE_ADVERSE_EVENTS tables.

Several data examples were updated to more accurately reflect "live" data.

Updates to Section 4: Value Revisions, pg. 16

4.1 OFF TREATMENT REASON, pg. 16: The word "toxicity" was changed to "Adverse Event" for the following valid value description: 03 = **Toxicity**/Side Effects/Complications

4.2 Therapy_Code from the PRIOR_THERAPIES Table, pg. 16: MedDRA v5.0 codes were added to the list of new values.

4.3 DOSE UNIT CODE, pg. 16: A value was added to accommodate dose units that are measured as cells.

Updates to Section 5: Changes to Field Attributes, pg. 18

5.2 COURSE_ID, pg. 18: This section was updated to reflect the change of the Course_ID field in the COURSE_AGENTS table as well as the TREATMENT_COURSES and ADVERSE_EVENTS tables. This section was also clarified to provide specific attribute information regarding Course_ID.

5.3 UNIT CODE, pg. 18: The table named in this section was updated to the COURSE_AGENTS table.

Updates to Section 6: New and/or Revised Business Rules, pg. 19

Business rules were updated to more accurately reflect the modifications made to the CDUS v3.0. Please refer to this version of the business rules; all previous versions are now obsolete.

Updates to Section 7: Clarifications/New Instructions for Data Submissions, pg. 24

7.1 RESPONSE INFORMATION, pg. 24, Item a: The word "requested" was changed to "mandatory" in the following sentence: If 'Other' is submitted, it is **requested** that information about the patient's response be submitted using the Gen_Response_Comments field as described in detail in the TRIAL_COMMENTS table section of the CDUS Instructions and Guidelines.

7.1 RESPONSE INFORMATION, pg. 24, Item c: The reference to the CDUS Abbreviated monitoring method was removed from the following sentence: The Observed_Date from the BEST_RESPONSES table is mandatory for all CDUS-Complete and **CDUS-Abbreviated** responses submitted, including Stable Disease.

7.3 SUBGROUP AND TREATMENT ASSIGNMENT CODES AND DESCRIPTIONS, pg. 24: This section was updated to include Correlative Study IDs.

7.4 SMART LOADER REMINDER, WARNING, AND SUSPENSION PROCESS, pg. 24: The word "warning" was removed from the following sentence: The CDU data resubmission timeline was modified for files with rejection or **warning** errors.

Updates to Appendix A: Summary List of Modifications

The summary was updated to reflect all clarifications described in this section. The following identifies specific updates made to the summary that are not reflected in any other section of this document.

CORRELATIVE_STUDIES Table, pg. A-1: A comment as added to clarify that correlative study information is mandatory *only* for protocols with embedded correlative studies.

PATIENTS Table, pg. A-2, Item 6: The Legacy Data Requirements column was updated to reflect that the Gender_Code field is required for all protocols.

PATIENTS Table, pg. A-2, Item 7: The Legacy Data Requirements column was updated to reflect that the Birth_Date field is required for all protocols. The Comments column was updated to reflect that this is a new reporting requirement.

PATIENTS Table, pg. A-2, Item 9: The column name change was added to the summary.

BASELINE_ABNORMALITIES Table, pg. A-4, Item 7: The Comments column was updated to remove the reference to version 3.0 of the NCI Common Toxicity Criteria (CTC).

Value Revisions, pg. A-5, Item 6: The reference to the NCI Common Toxicity Criteria (CTC), v3.0 was removed. CTEP is currently revising the NCI CTC, however the expected release date is undetermined at this time.

Response Information, pg. A-6, Item 1: The Reporting Requirements and Legacy Data Requirements columns were updated to provide specific requirements for response information.